MAR 2 8 2012

510K Summary

Date:	March 27, 2012
Submitter:	Zavation LLC 501 Avalon Way Brandon, MS 39047 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	John Walker
Type of 510(k) submission:	Special
Trade name:	Zavation IBF System
Common name:	Intervertebral Body Fusion Device
Classification regulation:	888.3080 (MAX, ODP)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	MAX, ODP

Purpose of Submission:
The purpose of this Special 510(k) is to add additional footprint sizes and lordotic angles to the Zavation CIF cage.

Device Description:
The Zavation IBF implants offers a variety of heights, widths and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone).

The Zavation IBF implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates.

Intended Use:
When used as a cervical intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature

patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (definded as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation IBF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Spinal System and Zavation Cervical Plate System.

Materials:
The devices are manufactured from medical grade PEEK Zeniva ZA-500(ASTM F2026) with Tantalum alloy position markers (ASTM F560).

Predicate Device:
Zavation IBF System, Zavation LLC (K112664)
LDR Spine Cervical Interbody Fusion System (K091088)

Technological Characteristics:
The Zavation IBF System possesses the same technological characteristics as the predicates. These include similar heights, widths, lengths, and intended use.

Performance Data:
Finite element analysis was performed to demonstrate that the components added to the Zavation IBF System in this 510(k) submission would not result in a new worst-case device. The finite element analysis method has been validated to testing performed per ASTM F2077. Results from this analysis demonstrates that the subject devices are substantially equivalent to the referenced predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 28 2012

Zavation LLC
% Mr. John Walker
501 Avalon Way
Brandon, Mississippi 39047

Re: K120576
Trade/Device Name: Zavation IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: February 24, 2012
Received: February 27, 2012

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3 – Indications for Use Statement

Indications for Use

510(k) Number: K120576

Device Name: Zavation IBF System

Indications For Use:

When used as a cervical intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (definded as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation IBF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120576